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|-----------------|-------------|----------------------|---------------------|------------------|
| 10/519,838 | 12/08/2005 | Eduardo N. Mitrani | 28888 | 9337 |

7590 08/10/2007
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| EXAMINER |
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KIM, TAEYOON

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| ART UNIT | PAPER NUMBER |
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1651

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08/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/519,838

Applicant(s)

MITRANI ET AL.

Examiner

Taeyoon Kim

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 174-218 is/are pending in the application.
- 4a) Of the above claim(s) 174-186, 190-206 and 213-218 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 187-189 and 207-212 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>10/19/05, 7/12/06, 12/4/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 174-218 are pending.

Election/Restrictions

Applicant's election without traverse of Group VI (claims 207-212) and "skin" as an elected species in the reply filed on 5/15/2007 is acknowledged.

Per applicant's request for reconsideration of the restriction requirement that Group IV (claims 187-189) be examined as well, the examiner rejoined the Group IV invention with the elected Group VI invention.

Claims 174-186, 190-206 and 213-218 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 187-189 and 207-212 have been considered on the merits.

Drawings

The drawings are objected to because the figures are not visible, especially for Figs. 1, 3, 8-13, 18-24 and 26-28. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary

to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 187-189 are objected to because of the following informalities: claim 187 discloses a step of "placing the tissue biopsy is said cutting chamber." It appears that the term "is" would be "in" instead. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 187-189 and 207-212 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "angiopump" in claim 188 is used by the claim to mean "micro-

organs processed, preferably verified for cell viability and prepared in a manner ready, but not necessarily utilized, for immediate administration”, while the accepted meaning is “an angioscopic fluid irrigation system,” according to Massoud et al. (2001). The term is indefinite because the specification does not clearly redefine the term.

Claim 187 and its dependents disclose the phrase “being operably coupled” in step (b) of the method in claim 187. It is not clear whether the phrase intends to claim physical coupling or functional coupling between the implanting mechanism and the cutting chamber.

Claim 187 discloses a limitation to the apparatus having an implanting mechanism. It is not clear how this subject matter limits the steps of the method claimed in the instant application, because the implanting mechanism in an apparatus is not required by the claimed method, or has no implication in the method of preparing micro-organ, rather it is for an intended use of micro-organ, which is not claimed, prepared by the method of instant invention. Since the limitation appears to be superfluous and unnecessary to the method claim, this limitation does not serve to particularly point out and distinctly claim the subject matter which applicant regards as their invention.

Claim 207 and its dependents disclose a step of decoupling the implanting device (see claim 207, line 15). It is not clear from which the implanting device is being detached. It appears that the implanting device is detached from the tissue cutter. However, without clarification, it could be interpreted that the implanting device is decoupled from micro-organ or tissue scraper.

Claim 207 discloses an intended use of a tissue scraper, which is for obtaining a

Art Unit: 1651

tissue biopsy. It is not clear how the tissue scraper can possibly obtain the biopsy. It is not clear whether the tissue scraper being used for tissue biopsy or just scraping tissue obtained via biopsy procedure. It appears that the step of scraping using the tissue scraper being carried out after actual tissue biopsy rather than obtaining tissue biopsy from a subject. Clarification is required.

Claim 208 discloses the phrase "automated travel mechanism for transferring the tissue biopsy from one region of said device to another". It is not clear what subject matter the phrase intends to point out. It can be interpreted that the tissue biopsy can be transferred from the scraper to the implanting device without going through the cutting chamber automatically. Clarification is required.

The terms "deepest" and "nearest" in claims 210 and 211 are relative terms which render the claim indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 210 and 211 disclose the term "surface" at the end of the claim. It is not clear what subject matter the term intends to point out. It is not clear of which surface the term claims. It could be interpreted as the surface of tissue biopsy, micro-organ or tissue cutter, etc.

Claims 207-212 are not clear whether the current claims are drawn to a method of generating micro-organs or a method of implanting micro-organs. Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 187-189 and 207-212 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitrani (US 5,888,720).

Claims 187-189 and 207-212 are drawn to a method of generating micro-organs from a tissue biopsy comprising providing an apparatus having a cutting chamber and an implanting mechanism, and placing the tissue biopsy in the chamber and cutting the biopsy into the plurality of micro-organs; a limitation to the micro-organs being operable as angiopumps; and a limitation to the apparatus having a viability testing chamber; a method for micro-organ preparation comprising scraping a skin tissue biopsy, cutting the tissue biopsy into plurality of fragments, forming micro-organs.

Mitrani teaches a method of generating micro-organs from skin biopsy by cutting the skin biopsy into multiple fragments with a suitable cutting means, forming micro-organs (see Fig. 1 and Example 1).

The limitation of the micro-organs being operable as angiopumps is not considered because this limitation is drawn to the intended use of micro-organs and since the product prepared by the method of Mitrani is identical with the current application, the micro-organs of Mitrani can be used for the intended use disclosed by the current application.

Although Mitrani does not particularly disclose a step of scraping tissue biopsy prior to cutting step, the method step of "cleaning fresh skin to remove underlying fat tissue and cut into 0.4x5 cm flaps, which are then transversely sectioned, using a tissue chopper or other suitable cutting means" as disclosed in Example 1 of Mitrani teaches scraping and cutting steps of the current invention.

The last two steps of "mounting said micro-organ..." and "decoupling said at least one implanting device" in claim 207 and its dependents appear to be superfluous to the method of generating micro-organs, and do not provide any active step for generating micro-organs per se. Therefore, these two steps do not make the current invention unobvious.

Mitrani also teaches various different tissue sources including skin, liver, kidney, etc. However, the selection of tissue biopsy sources does not provide any active step in the method of generating micro-organs.

Mitrani teaches the thickness of micro-organs formed being 300 micron (see

Art Unit: 1651

Example 1). However, a person of ordinary skill in the art would have considered that the limitation of thickness of tissue biopsy by cutting step to form micro-organs would be result-effective variables. As such, the variables would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by those references.

Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In *re* Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); >see also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); ** In *re* Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In *re*

Art Unit: 1651

Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Although Mitrani does not teach the limitation of "a split-thickness tissue biopsy," it would have been obvious for a person of ordinary skill in the art to use a split-thickness tissue biopsy.

The skilled artisan would have been motivated to make such a modification because a person of ordinary skill in the art would recognize that the selection of different types of tissue biopsy (e.g. split-thickness and full-thickness) would have been readily optimized in practicing the invention disclosed by the reference.

Furthermore, the selection of either split-thickness biopsy or full-thickness biopsy does not provide patentable weight to the method claims of the current invention.

Applicant's invention in claim 187 require that the apparatus utilized in the method have an "implanting mechanism" however there is no actual use of said mechanism in the claimed method. As such the "implanting mechanism" serves no purpose for the instant method and thus is functionally ornamentation. In *In re Seid*, 161 F.2d 229, 73 USPQ 431 (CCPA 1947), the court found that matters relating to ornamentation only which have no mechanical function cannot be relied upon to patentably distinguish the claimed invention from the prior art.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Art Unit: 1651

Conclusion

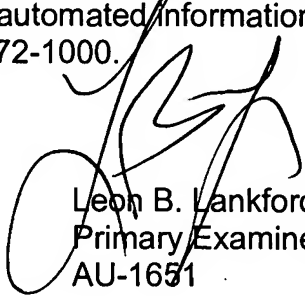
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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